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Date: September 12, 2005**To:** Examiner Sabiha Naim Qazi
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9/12/05 *Melba Fuentes*
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Attached please find the following documents for the above referenced patent
application:

- 1) Response to Notice to Non-Compliant Appeal Brief Dated
9/7/2005 [1 page]; and
- 2) Supplemental Appeal Brief [30 pages].

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Patent
Attorney Dkt. No.: LYNN/0120IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCESIN RE APPLICATION OF:
Waheguru Pal Singh, *et al.*

SERIAL NO. 09/733,611

FILED: December 8, 2000

FOR: Methods of Sterilizing with
Dipercarboxylic Acids§ CONFIRMATION NO.: 4196
§
§ EXAMINER: Qazi, Sabiha Naim
§
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§ GROUP ART UNIT: 1616
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SUPPLEMENTAL APPEAL BRIEF

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APPEAL BRIEF

Appellant timely filed a Notice of Appeal to the Board on August 24, 2004 appealing the decision of the Examiner in the Final Office Action dated February 26, 2004. Appellant timely filed its Appeals Brief and the Examiner then reopened prosecution. Appellant filed a Request to Reinstate Appeal on May 4, 2005 appealing the decision of the Examiner in the Final Office Action dated April 13, 2005. Appellant submits this Appeal Brief on May 4, 2005 in compliance with 37 CFR 41.37.

(1) REAL PARTY IN INTEREST

The real party of interest in this action is Lynntech International, Ltd., the recorded assignee of the entire right, title and interest in and to the patent application now under appeal before this Board. Lynntech International, Ltd. is a limited partnership of the State of Texas having a place of business at College Station, Texas.

(2) RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant, Appellant's legal representative, or Assignee that will affect or be directly affected by or have a bearing upon the Board's decision in the pending appeal.

(3) STATUS OF THE CLAIMS

The status of all pending claims in the application under appeal is as follows: claims 1-10, 17, 26-38, 40-49 and 51 are pending and stand rejected. Rejected claims 1-10, 17, 26-38, 40-49 and 51 are under appeal. Claims 11-16, 18-25, 39 and 50 have been cancelled.

(4) STATUS OF AMENDMENTS

No amendments have been filed subsequent to the final rejection.

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(5) SUMMARY OF CLAIMED SUBJECT MATTER

Appellant identified a need for methods that would provide effective sterilizing solutions. (Specification, p. 3, ln. 19-24). An effective sterilizing solution is one that is without cause for concern as to the stability or shelf-life of the sterilizing solution or its transportation as a hazardous and bulky solution. *Id.* Appellant determined that a desirable sterilizing solution would be one that (1) could be formed from a stable, solid peracid formulation, (2) did not contain the reagents or chemicals used in formation of the peracid, and (3) could be formed from a peracid that was soluble enough in water to obtain an aqueous solution having a peracid concentration high enough to be a sterilizing solution. *Id.*

Peracids are potent biocides that have a broad-spectrum killing potential that decompose upon use into chemically benign end products. (Specification, p. 2, ln. 11-15). Prior art formulations of peracid sterilizing solutions contained low molecular weight peracids that were pungent and possessed high volatility. *Id.* As Appellant pointed out, by citing Eggersperer, *et al.*, U.S. Patent No. 4,129,517, those having ordinary skill in the art believed that peracids having a molecular weight high enough to form a stable solid could not be dissolved in water at concentrations high enough to form a sterilizing solution. *Id.* at 19-28.

However, contrary to the beliefs of Eggersperer and others, Appellant found that there are peracids that are stable as a solid at room temperature and that can be dissolved at concentrations high enough to form aqueous sterilizing solutions. (Specification, p. 3, ln. 28-30). Solutions made with these dipercarboxylic acids are characterized by effectiveness against a broad spectrum of microorganisms, including but not limited to mycobacteria, yeasts, fungi, viruses and resistant bacteria spores. (Specification, p. 4, ln. 5-10).

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To understand the value of this invention, it is imperative to distinguish between sterilization and disinfection – sterilization uses physical or chemical means to destroy all microbial life while disinfection destroys some, but not all microbial life. *Id.* at 11-15. If a chemical disinfectant can reduce the level of bacterial endospores by six logarithms or more, it is considered to be a liquid sterilant. *Id.* at 19-21. Therefore, sterilization does not only destroy microbes but also *spores*, which are much more difficult to destroy.

Appellant demonstrated that certain solid dipercarboxylic acids were soluble in water at sterilization levels. (Specification, p. 9, ln. 1-5 and FIG. 1). In FIG. 1, Appellant further showed that a 10% diperglutaric acid solution killed all spores almost immediately and that a 0.8% dipersuberic solution killed all spores after about 10 minutes of exposure to the sterilizing solution by the spores. (FIG. 1). Therefore, Appellant demonstrated that certain dipercarboxylic acids could be formed into a solid and then dissolved in water at sufficient concentration to form a sterilizing solution. Furthermore, Appellant has shown that concentrations of dipercarboxylic acid that are not between at least 0.1 wt. % and saturation *do not form* a sterilizing solution. (FIG. 1).

Appellant claim a method of preparing a sterilizing solution that includes storing dry solid material comprising one or more dipercarboxylic acids and dissolving this material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 wt% and saturation. (Claim 1).

The select subset of dipercarboxylic acids are unique sterilizing agents because they can form dry solid particulates at ambient conditions, yet are readily dissolved in water with minimal agitation, such as stirring. (Specification, p. 7, ln. 1-4). Furthermore, this subset of dipercarboxylic acids can be stored as a solid for extended periods without degradation. *Id.*

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Examples of dry dipercarboxylic acids that may be used in the claimed method of Appellants include diperglutaric acid (C5), diperadipic acid (C6), diperpimelic acid (C7), dipersuberic acid (C8), and diperazelaic acid (C9). (Specification, p. 4, ln. 4-5). The parenthetical "C" number provides the number of carbon atoms in the dipercarboxylic acid.

Because the dipercarboxylic acids used in the method of the present invention to form a sterilizing solution are first stored as a dry solid, the solid material that comprises one or more dipercarboxylic acids is substantially free from other organic compounds other than the dipercarboxylic acids. (Claim 4). One of the problems of the prior art peracid sterilizing solutions was that these solutions also contained hydrogen peroxide, which was part of the equilibrium mixture resulting from the formation of the peracid. (Specification, p. 3, ln. 10-18). For example, commercially available preparations of peracetic acid contain from 7 to 25 % hydrogen peroxide and from 6 – 40 % acetic acid. *Id.* Appellant specifically claim that the sterilizing solution is free of hydrogen peroxide. (Claim 6). Alternatively, Appellant claim that the solid dry material comprises sterilizing agents consisting essentially of one or more dipercarboxylic acids, thereby excluding hydrogen peroxide as well as any other active sterilizing agent. (Claim 41).

Therefore, the claims under examination provide methods for the preparation of sterilizing solutions that include, *inter alia*, the steps of storing a dry solid material comprising dipercarboxylic acids and dissolving this material into water to form an aqueous sterilizing solution (Claims 1, 30) and in another claimed embodiment, storing dry material comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids. (Claim 41).

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(6) GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

a. Claims 1-10, 17, 26-38, 40-49 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,200,189 issued to Oakes, *et al.* in view of U.S. Patent No. 5,049,298 issued to Ploumen, *et al.*

b. Claims 1-10, 17, 26-38, 40-49 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,415,668 issued to Lagnemo, *et al.*

(7) ARGUMENT

a. Claims 1-10, 17, 26-38, 40-49 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,200,189 issued to Oakes, *et al.* in view of U.S. Patent No. 5,049,298 issued to Ploumen, *et al.*

(1) Review of the cited prior art. Oakes discloses a peroxyacid antimicrobial liquid concentrate that can be diluted with water to form a composition useful for sanitizing fixed processing lines in dairies, breweries and other food processing operations. (Oakes, Abstract). Oakes discloses a concentrate composition which is diluted to a "use" solution prior to its utilization as a sanitizer. (Oakes, col. 6, lines 24-26). Oakes discloses a range of preferred concentrations of the peroxyacids in the sanitizing solution as up to about 75 ppm, which is about .0075 wt%. (Oakes, col. 1, lines 60-65). Oakes further discloses that the peroxyacid component is obtained by reacting carboxylic acids with hydrogen peroxide to form a concentrate that is then diluted with water to provide the use solution. (Oakes, col. 6, lines 39-51). Oakes discloses peroxyacids that were tested by diluting them with water. (Oakes, col. 8, Table I). All the concentrates disclosed by Oakes are liquids, not solids and are used to produce a sanitizing solution, not a sterilizing solution. Furthermore, Oakes discloses that the concentrate includes hydrogen peroxide in quantities between 1 to 50 wt. %. (Oakes, col. 4, lines 25-28).

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Ploumen discloses bleaching granules containing a solid, *water-insoluble* peroxy acid. (Ploumen, Abstract [Emphasis added]). Ploumen discloses a process that comprises, *inter alia*, mixing a water-insoluble organic peroxy acid and a hydratable inorganic material. . . (Ploumen, col. 2, lines 45-55). Ploumen discloses preferred water-insoluble peracids. (Ploumen, col. 4, lines 50-68). Ploumen further discloses that when these water-insoluble peracids are formed into granules with other materials, the granules are dissolved in water by conversion of the peracid into its soluble neutralized salt, thereby forming a solution that has peracid content at all. (Ploumen, col. 7, lines 15-20).

(2) Applicable law. A claimed invention is unpatentable if the differences between it and the prior art "are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. 103(a) [emphasis added]. As the Federal Circuit has stated, "Focusing on the obviousness of substitutions and differences instead of on the invention *as a whole* . . . was a legally improper way to simplify the difficult determination of obviousness." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383 (Fed. Cir. 1986) [emphasis added].

To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974). All words in a claim must be considered in judging the patentability of that claim against the prior art. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970).

Another requirement for providing a *prima facie* case of obviousness is that the Examiner must provide a basis for combining or modifying the cited references. In the case *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), the Court states:

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When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. Although the suggestion to combine references may flow from the nature of the problem, the suggestion more often comes from the teachings of the pertinent references or from the ordinary knowledge of those skilled in the art that certain references are of special importance in a particular field. Therefore, when determining the patentability of a claimed invention which combines two known elements, the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.

Id. at 1356 [citations omitted].

In the case *In re Lee*, 277 F.3d 1338 (Fed. Cir. 2002), the Federal Circuit held:

When patentability turns on the question of obviousness, the search for and analysis of the prior art includes *evidence* relevant to the finding of whether there is a teaching, motivation, or suggestion to select and combine the references relied on as evidence of obviousness.

Id. at 1343, emphasis added.

In the case *In re Kotzab*, 217 F.3d 1365 (Fed. Cir. 2000), the Court distinctly points out the requirement that particular findings are required as to the justification of combining or modifying references. The Court stated:

Even when obviousness is based on a single prior art reference, there must be a showing of a suggestion or motivation to modify the teachings of that reference. The motivation, suggestion or teaching may come explicitly from statement in the prior art, the knowledge of one of ordinary skill in the art, or, in some cases the nature of the problem to be solved. In addition, the teaching, motivation or suggestion may be implicit from the prior art as a whole, rather than expressly stated in the references . . . The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art . . . Whether the Board relies on an express or an implicit showing, it must provide particular findings related

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thereto. Broad conclusory statements standing alone are not evidence.

Id. at 1370

The case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching, suggestion, or motivation to combine prior art references. *See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998) (describing “teaching or suggestion or motivation [to combine]” as an “essential evidentiary component of an obviousness holding”); *In re Rouffet*, 149 F.3d 1350, 1359, 47 USPQ2d 1225, 1232 (Fed. Cir. 1998) (“the Board must identify specifically....the reasons one of ordinary skill in the art would have been motivated to select the references and combine them”); and *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination “only by showing some objective teaching [leading to the combination]”).

Further considering the impermissible use of hindsight obviousness analysis in the case *In re McLaughlin*, 443 F.2d 1392 (CCPA 1971), the Court stated:

It should be too well settled now to require citation or discussion that the test for combining references is not what the individual references themselves suggest but rather what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. Any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made *and does not include knowledge gleaned only from applicant's disclosure*, such a reconstruction is proper.

Id. at 1395, emphasis added.

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(3) The cited prior art references do not teach or suggest all the limitations of the claimed invention. Appellant claims methods comprising, *inter alia*, storing dry solid material comprising one or more dipercarboxylic acids and dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation. (Claims 1 and 30). Appellant further claims a nearly identical method except that the dry solid material comprises sterilizing agents consisting essentially of one or more dipercarboxylic acids. (Claim 41). Claim 30 further includes the limitation of "in the absence of a peroxide." (Claim 30). Appellant further claims that the amount of solid material dissolved into the water is sufficient to be sporicidal (Claim 8) and that the dissolved amount is sufficient to be sterilizing. (Claim 9).

Neither of the cited prior art references teach or suggest an aqueous *sterilizing* solution as claimed by Appellant. Oakes discloses only *sanitizing* solutions having concentrations of up to 75 ppm, or about 0.0075 percent concentration. Appellant claims a sterilizing solution having a concentration of between about 0.1 wt percent and saturation. Ploumen discloses water-insoluble peroxy acids that are useful as *bleaching* compositions. Ploumen does not teach or suggest that the aqueous bleaching solution may be used as an aqueous sterilizing solution.

Appellant has shown that concentrations that are not between 0.1 wt. % and saturation of dipercarboxylic acid, that is that are less than about 0.1 wt. %, do not form sterilizing solutions. (See, Specification, FIG. 1).

Furthermore, neither of the cited prior art reference teach or suggest a solid dipercarboxylic acid that is soluble in water to form an aqueous sterilizing solution having a concentration of the dipercarboxylic acid of at least 0.1 weight percent, a limitation claimed by Appellant. Oakes only discloses liquid concentrates that can be diluted with water. Ploumen

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only discloses *water-insoluble* peroxy acids. Water insoluble peroxy acids cannot be used as a solid that is dissolved in water with a concentration between about 0.1 wt. % and saturation because *they can't be dissolved*.

Neither of the cited prior art references teach or suggest Appellant's claimed limitations of *dissolving* dry dipercarboxylic acids into water to prepare an aqueous *sterilizing* solution having a dipercarboxylic acid content between about *0.1 weight percent* and saturation. Neither of the cited prior art references teach or suggest that the solutions disclosed therein can be useful as a sporicidal solution (Claim 8) or as a sterilizing solution (Claims 1, 9, 30, 41). Since a *prima facie* case of obviousness requires that all claim limitations must be taught or suggested by the prior art and all words in a claim must be considered in judging the patentability of that claim against the prior art, Appellant respectfully asserts that a *prima facie* case of obviousness has not been presented. Therefore, Appellant respectfully requests this Board to find that the claims presented on appeal are patentable.

(4) The Examiner has presented no evidence of a teaching, suggestion or motivation to combine the cited prior art references. Appellant respectfully asserts that the Examiner has failed to provide a *prima facie* case of obviousness for failure to provide the required *evidence* of the teaching, suggestion or motivation to select and combine the references relied on as evidence of obviousness. *Lee*, 277 F.3d at 1343. The Examiner has provided no statement or evidence of the teaching, suggestion or motivation to select and combine or modify the cited prior art references. The Examiner merely states: "Both references teach dipercarboxylic acid compositions, which embrace the Applicant's claimed invention." (Final Office Action, p. 2). The Examiner further states:

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The instant invention differs from the prior art in that the presently claimed invention is using the dipercarboxylic acid in solid form and using it as a sterilant in aqueous form while the prior art teaches the same aqueous composition for use as peroxyacid antimicrobial concentrates for sanitizing surfaces. . . (OAKES et al). The prior art teaches the solid form of peroxyacids in the form of granules or powder (PLOUMEN et al).

Final Office Action, p. 3.

These statements fail to provide any evidence of the motivation to combine or modify the prior art references. The Examiner fails to point out that Ploumen discloses only *water-insoluble* peroxy acids and Appellant claims *dissolving* the solid dipercarboxylic acid in water.

As Appellant has disclosed, the prevailing thought in the art of sterilants was that dipercarboxylic acids having a molecular weight high enough to make into a solid were not soluble enough to be useful as a sterilizing agent. (Specification, page 2. lines 19-28). The prior art references cited by the Examiner, which disclose water-insoluble peroxyacids and liquid concentrate of dipercarboxylic acids, support Appellant's assertion as to the prevailing attitude of those having ordinary skill in the art. There is no suggestion or teaching to modify or combine the cited prior art references to arrive at Appellant's claimed invention.

Appellant respectfully asserts that a *prima facie* case of obviousness has not been presented because the Examiner has failed to provide any mention or evidence of the motivation to combine or modify the cited prior art references. Therefore, Appellant respectfully requests this Board to find that the claims presented on appeal are patentable.

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b. Claims 1-10, 17, 26-38, 40-49 and 51 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,415,668 issued to Lagnemo, et al.

(1) Review of the cited prior art. Lagnemo discloses esters that are useful as a bleach. (Abstract). The disclosed esters, diacylated dipercarboxylic acids, are not dipercarboxylic acids but are instead esters that are formed by reacting a dipercarboxylic acid with other reactants in a chemical reaction to form an ester, the structure of which is shown in the Abstract. (Lagnemo, Abstract). Lagnemo discloses that there are some of these esters that are useful as bleaches because they are soluble in water to concentrations useful as a bleach. (Lagnemo, col. 2, lines 20-47). Lagnemo further discloses that useful bleaching amounts are 0.12 g of a diacylated dipercarboxylic acid or alternatively, double that amount, 0.24 g, per 1000 ml of water. (Lagnemo, col. 18, lines 16-35). The higher concentration, 0.24 g/L, provides a concentration of about 0.024 wt% diacylated dipercarboxylic acid in water.

Furthermore, Lagnemo discloses that the ester undergoes hydrolysis when placed in *alkaline* aqueous solutions so that it breaks down into dipercarboxylic acids *and* percarboxylic acids and when hydrogen peroxide is present, two moles of the ester forms 2 moles of percarboxylic acid and one mole of dipercarboxylic acid. (Lagnemo, col. 2, lines 10-20).

As indicated above, the hydrolysis required to convert the esters disclosed by Lagnemo to the mixture of percarboxylic acid and dipercarboxylic acid occurs in an alkaline aqueous solution. Therefore, an alkaline agent must also be supplied when using the esters disclosed by Lagnemo to provide a pH in the range of about 9 to about 12. (Lagnemo, col. 10, lines 3-10).

(2) The cited prior art reference does not teach or suggest all the limitations of the claimed invention. Appellant claims methods comprising, *inter alia*, storing dry solid material comprising one or more dipercarboxylic acids and dissolving the dry solid material into water as

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needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation. (Claims 1 and 30). Appellant further claims a nearly identical method except that the dry solid material comprises sterilizing agents consisting essentially of one or more dipercarboxylic acids. (Claim 41). Claim 30 further includes the limitation of "in the absence of a peroxide." (Claim 30). Appellant further claims that the amount of solid material dissolved into the water is sufficient to be sporicidal (Claim 8) and that the dissolved amount is sufficient to be sterilizing. (Claim 9).

Appellant respectfully asserts that a *prima facie* case of obviousness has not been presented because Lagnemo does not teach or suggest storing a dry solid material comprising one or more dipercarboxylic acids, which is one of the limitations claimed by Appellant. Instead, Lagnemo discloses an *ester* that was synthesized by reacting a dipercarboxylic acid with other ingredients to form the ester, a diacylated dipercarboxylic acid.

Furthermore, Lagnemo does not disclose a *sterilizing* solution but discloses only that the ester may be dissolved in water in sufficient quantity to provide a *bleaching* solution. As the entire prosecution of this application has shown, those having ordinary skill in the art knew at the time of Appellant's invention that solid dipercarboxylic acids could be dissolved in water to form bleaching solutions having concentrations of dipercarboxylic acids necessary to form a *bleaching* solution. However, such bleaching concentrations are much lower than the concentration required to obtain a sterilizing solution, which is greater than 0.1 wt. %. (See, Specification, FIG. 1).

As Appellant disclosed in the Specification, at the time of Appellant's invention, those having ordinary skill in the art were not aware that dipercarboxylic acids could be stored as a solid and then dissolved in water when needed in sufficient quantity to form a *sterilizing*

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solution. Lagnemo provides examples of *bleaching* solutions but provides neither examples nor any suggestion or teaching that a *sterilizing* solution may be produced using the disclosed esters. A sterilizing solution is a sporicidal solution, another limitation claimed by Applicant that is not taught or suggested by the cited prior art. (Claim 9).

Furthermore, Lagnemo discloses that upon hydrolysis, the resulting product is not a dipercarboxylic acid as claimed by Appellant but instead a *mixture* of percarboxylic acids and dipercarboxylic acids.

Lagnemo fails to teach or suggest all of Appellant's claimed limitations of dissolving dry *dipercarboxylic acids* into water to prepare an aqueous *sterilizing* solution having a *dipercarboxylic acid* content between about 0.1 weight percent and saturation. Appellant further claims that adequate dry material is dissolved into water to form a sporicidal solution (Claim 8) and a sterilizing solution (Claim 9). Since a *prima facie* case of obviousness requires that all claim limitations must be taught or suggested by the prior art and all words in a claim must be considered in judging the patentability of that claim against the prior art, Appellant respectfully asserts that a *prima facie* case of obviousness has not been presented. Therefore, Appellant respectfully requests this Board to find that the claims presented on appeal are patentable.

(3) The Examiner has presented no evidence of a teaching, suggestion or motivation to modify the cited prior art reference. Appellant respectfully asserts that the Examiner has failed to provide a *prima facie* case of obviousness for failure to provide the required *evidence* of the teaching, suggestion or motivation to select and combine the references relied on as evidence of obviousness. *Lee*, 277 F.3d at 1343. The Examiner has provided no statement or evidence of the teaching, suggestion or motivation to select and combine or modify the cited prior art references. As the *Kotzab* court has stated: "Even when obviousness is based on a single prior art reference,

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there must be a showing of a suggestion or motivation to modify the teachings of that reference.”

In re Kotzab, 217 F.3d at 1370.

The Examiner has merely stated that “It would have been obvious to one skilled in the art at the time the invention was made to prepare additional beneficial compositions in solid or aqueous form because the prior art teaches it for the reasons cited above.” (Final Office Action, p. 5).

Such broad conclusory statements do not provide the evidence of the teaching, suggestion or motivation to select and modify the cited prior art references that is required to provide a *prima facie* case of obviousness. As the *Kotzab* court instructed:

Whether the Board relies on an express or an implicit showing, it must provide particular findings related thereto. Broad conclusory statements standing alone are not evidence.

Id.

One having ordinary skill at the time that Appellant conceived the claimed invention thought that there were no dipercarboxylic acids that could (1) be formed into a solid and stored until needed to prepare a sterilizing solution and then (2) dissolved in water at high enough concentrations to form a sterilizing solution. It was known at the time that such materials could be formed and utilized as bleaching agents because bleaching solutions are much weaker in concentration than sterilizing solutions. The Examiner has provided no evidence that one having ordinary skill at the time of the claimed invention would modify Lagnemo to change the ester into a dipercarboxylic acid and then utilize the dicarboxylic acid as a sterilant.

Appellant respectfully asserts that a *prima facie* case of obviousness has not been presented because the Examiner has failed to provide any mention or evidence of the motivation

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to modify the cited prior art reference. Therefore, Appellant respectfully requests this Board to find that the claims presented on appeal are patentable.

(4) The rejection is based upon impermissible hindsight analysis by the Examiner. There being no evidence of a teaching, suggestion or motivation to combine the cited references, Appellant respectfully asserts that the Examiner has fallen into the hindsight trap, using Appellant's specification as the motivation to combine the cited references. As the courts have instructed, the case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching, suggestion, or motivation to combine prior art references. *C.R. Bard*, 157 F.3d at 1352. Any judgment of obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning, but so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made *and does not include knowledge gleaned only from applicant's disclosure*, such a reconstruction is proper. *McLaughlin*, 443 F.2d at 1395.

Appellant has disclosed the benefit of certain dipercarboxylic acids that are capable of being stored as a dry material and the dissolved in water in sufficient quantity to form a sterilizing solution when needed. Appellant has disclosed that those having ordinary skill in the art at the time that Appellant conceived the claimed method believed that there were no dipercarboxylic acids that could be stored as a solid and then dissolved in sufficient quantity to form a sterilizing solution. Indeed, the Examiner has only provided prior art references that support Appellant's contention. The prior art references that disclose using dipercarboxylic acids as sanitizers or disinfectants only use liquid dipercarboxylic acids, not solids, and the only prior art references that the Examiner has presented that use solid dipercarboxylic acids are used

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for bleaching, at much lower concentrations. Without the disclosure by Appellant, there is no teaching, suggestion or motivation to modify the cited reference. Without this knowledge gleaned only from the Appellant's disclosure, there would be no motivation, suggestion or teaching to combine the cited references.

Because the Examiner has used information gleaned only from Appellant's specification, using Appellant's specification as a blueprint to focus on the obviousness of substitutions and differences instead of the invention as a whole, Appellant respectfully asserts that the Examiner has impermissibly used hindsight analysis to reject Appellant's claims. Therefore, Appellant respectfully requests that this Board find that the claims submitted on appeal are patentable.

(c) Summary. Appellant respectfully asserts that the Examiner has failed to provide a *prima facie* case of obviousness for the reasons that follow.

1. The prior art citations of Oakes and Ploumen do not teach or suggest each and every limitation of the claimed invention of Appellant. Oakes discloses only *sanitizing* solutions having concentrations of up to 0.0075 percent concentration and Ploumen discloses using only *water-insoluble* peroxy acids for *bleaching* compositions. Neither of these cited prior art references teach Appellant's claimed limitations of dissolving dry dipercarboxylic acids into water to prepare an aqueous sterilizing solution having a dipercarboxylic acid content of between about 0.1 wt. % and saturation.

2. The Examiner has provided no statement or evidence of the teaching, suggestion or motivation to select and combine or modify the Oakes and/or Ploumen. As Appellant has disclosed, the prevailing thought in the art of sterilants at the time that Appellant conceived the claimed invention was that dipercarboxylic acids having a molecular weight high enough to

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make into a solid were not soluble enough to be useful as a sterilizing agent. The Examiner has provided no evidence from Oakes or Ploumen that would lead one having ordinary skill in the art to modify or combine Oakes or Ploumen.

3. Lagnemo does not teach or suggest each and every limitation claimed by Appellant. Lagnemo does not teach or suggest storing a dry solid material comprising one or more dipercarboxylic acids. Instead Lagnemo disclosed storing an ester formed as a product of a reaction with dipercarboxylic acids. Lagnemo also only discloses the use of the disclosed esters as bleaching components, and used at concentrations useful for bleaching solutions, not sterilizing components dissolved at concentrations required to form a sterilizing solution as claimed by Appellant.

4. The Examiner has presented no evidence of a teaching or suggestion or motivation to modify Lagnemo, which addresses the use of esters as a bleaching component in a bleaching solution.

5. Appellant respectfully assert that the Examiner has lost track of the "subject matter as a whole" and has impermissibly focused on the obviousness of substitutions and differences instead of focusing on the invention as a whole. Using impermissible hindsight analysis, the Examiner has sought to find in the cited references the limitations claimed by Appellant without regard either to what the cited references teach or what the Appellant's claimed invention is as a whole.

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WHEREFORE, Appellant respectfully request that this Board find that claims 1-10, 17, 26-38, 40-49 and 51 presented on appeal are patentable.

Respectfully submitted,



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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

IN RE APPLICATION OF:
 Waheguru Pal Singh, *et al.*

SERIAL NO. 09/733,611

FILED: December 8, 2000

FOR: Methods of Sterilizing with
 Dipercarboxylic Acids

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EXAMINER: Qazi, Sabiha Naim

GROUP ART UNIT: 1616

APPENDIX IN SUPPORT OF APPELLANT'S APPEAL BRIEF

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APPENDIX A
(8) CLAIMS APPENDIX

What is claimed is:

1. (original) A method of preparing a sterilizing solution, comprising:
 - (a) storing dry solid material comprising one or more dipercarboxylic acid; and
 - (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.
2. (original) The method of claim 1, wherein the solid material further comprises inorganic salts.
3. (original) The method of claim 2, wherein the inorganic salts are provided in a stabilizing amount.
4. (original) The method of claim 1, wherein the solid material is substantially free from organic compounds other than the one or more dipercarboxylic acid.
5. (original) The method of claim 1, wherein the one or more dipercarboxylic acid is soluble in water in the absence of a solubilizer.
6. (original) The method of claim 1, wherein the sterilizing solution is substantially free of hydrogen peroxide.
7. (original) The method of claim 1, wherein the one or more dipercarboxylic acid is selected from diperglutaric acid, diperadipic acid, diperpimelic acid, dipersuberic acid, and diperazelaic acid, and combinations thereof.

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8. (original) The method of claim 1, wherein the amount of solid material dissolved into water is sufficient to be sporicidal.

9. (original) The method of claim 1, wherein the amount of solid material dissolved into water is sufficient to be sterilizing.

10. (original) The method of claim 1, wherein the water is at ambient temperature.

11-16. (canceled).

17. (original) The method of claim 1, wherein the dry solid material further comprises one or more organic solubilizers selected from long chain aliphatic fatty acids, long chain aliphatic quaternary ammonium salts, and combinations thereof.

18-25. (canceled)

26. (previously presented) The method of claim 1, further comprising:

contacting a surgical instrument with the sterilizing solution, wherein the surgical instrument becomes sterilized.

27. (previously presented) The method of claim 1, further comprising:

contacting a device with the sterilizing solution, wherein the device becomes sterilized.

28. (previously presented) The method of claim 1, wherein the step of dissolving further comprises:

stirring the sterilizing solution, wherein the stirring facilitates the dissolving of the dry solid material.

29. (previously presented) The method of claim 1, further comprising:

contacting a lumen of an endoscope with the sterilizing solution, wherein the lumen becomes sterilized.

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30. (previously presented) A method of preparing a sterilizing solution, comprising:
- (a) storing dry solid material comprising one or more dipercarboxylic acid; and
 - (b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation, in the absence of a peroxide.
31. (previously presented) The method of claim 30, wherein the solid material further comprises inorganic salts.
32. (previously presented) The method of claim 31, wherein the inorganic salts are provided in a stabilizing amount.
33. (previously presented) The method of claim 30, wherein the solid material is substantially free from organic compounds other than the one or more dipercarboxylic acid.
34. (previously presented) The method of claim 30, wherein the one or more dipercarboxylic acid is soluble in water in the absence of a solubilizer.
35. (previously presented) The method of claim 30, wherein the one or more dipercarboxylic acid is selected from diperglutaric acid, diperadipic acid, diperpimelic acid, dipersuberic acid, and diperazelaic acid, and combinations thereof.
36. (previously presented) The method of claim 30, wherein the amount of solid material dissolved into water is sufficient to be sporicidal.
37. (previously presented) The method of claim 30, wherein the amount of solid material dissolved into water is sufficient to be sterilizing.
38. (previously presented) The method of claim 30, wherein the water is at ambient temperature.

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39. (canceled).

40. (previously presented) The method of claim 30, wherein the dry solid material further comprises one or more organic solubilizers selected from long chain aliphatic fatty acids, long chain aliphatic quaternary ammonium salts, and combinations thereof.

41. (previously presented) A method of preparing a sterilizing solution, comprising:

(a) storing dry solid material comprising sterilizing agents consisting essentially of one or more dipercarboxylic acids; and

(b) dissolving the dry solid material into water as needed to prepare an aqueous sterilizing solution having a dipercarboxylic acid concentration between about 0.1 weight percent and saturation.

42. (previously presented) The method of claim 41, wherein the solid material further comprises inorganic salts.

43. (previously presented) The method of claim 42, wherein the inorganic salts are provided in a stabilizing amount.

44. (previously presented) The method of claim 41, wherein the solid material is substantially free from organic compounds other than the one or more dipercarboxylic acid.

45. (previously presented) The method of claim 41, wherein the one or more dipercarboxylic acid is soluble in water in the absence of a solubilizer.

46. (previously presented) The method of claim 41, wherein the one or more dipercarboxylic acid is selected from diperglutaric acid, diperadipic acid, diperpimelic acid, dipersuberic acid, and diperazelaic acid, and combinations thereof.

47. (previously presented) The method of claim 41, wherein the amount of solid material dissolved into water is sufficient to be sporicidal.

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48.(previously presented) The method of claim 41, wherein the amount of solid material dissolved into water is sufficient to be sterilizing.

49. (previously presented) The method of claim 41, wherein the water is at ambient temperature.

50. (canceled).

51. (previously presented) The method of claim 41, wherein the dry solid material further comprises one or more organic solubilizers selected from long chain aliphatic fatty acids, long chain aliphatic quaternary ammonium salts, and combinations thereof.

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(9) Appendix B – EVIDENCE APPENDIX

NONE

(10) Appendix C – RELATED PROCEEDINGS APPENDIX

NONE